

K080932

Pg 1 of 2

**510(k) Summary for the
Lutronic Corporation MOSAIC Laser System**

JUN - 9 2008

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

<u>Submitter:</u>	Lutronic Corporation #403-2,3,4, IIsan Technotown 1141-1 Baeksok-Dong, IIsan-Gu Goyang-Si, Gyeonggi-Do, 410-722 Republic of Korea
<u>Contact Person:</u>	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-824-2541
<u>Summary Preparation Date:</u>	March 31, 2008

2. Names

<u>Device Name:</u>	MOSAIC Laser System
<u>Classification Name:</u>	Laser Instrument, Surgical, Powered Product Code: GEX Panel : General & Plastic Surgery

3. Predicate Devices

The MOSAIC Laser System is substantially equivalent to a combination of the MOSAIC Laser System (K070392) and the Fraxel II SR Laser System and Accessories (K062303).

4. Device Description

The MOSAIC Laser System consists of a self-contained console, an optical fiber delivery system and a footswitch. The MOSAIC produces a beam of coherent infrared (1550 nm) light. The physician can optimize the effect for different applications by controlling the power of the laser pulse and using a different handpiece tip (5 mm, 6 mm, 8 mm, and 10 mm).

The system console is the heart of the MOSAIC Laser System and contains the optical system (Er-GLASS Fiber Laser Module), Touch LCD, handpiece, system control module with an embedded processor, and power supply module. The main console also includes a key switch used to turn the power on and off, an emergency stop push button that quickly de-energizes the system in emergency situations, and the Touch LCD.

5. Indications for Use

The MOSAIC Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue.

6. Performance Data

Performance data was supplied which showed that the device has similar histological effects as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2008

Lutronic Corporation
% O'Connell Regulatory Consultants, Inc.
Ms. Maureen O'Connell
Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

Re: K080932

Trade/Device Name: MOSAIC Laser System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: May 12, 2008

Received: May 13, 2008

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Ms. Maureen O’Connell

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometric’s (OSB’s) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080932

Page 1 of 1

Indications for Use

510(k) Number (if known): K080932

Device Name: MOSAIC Laser System

Indications for Use:

The MOSAIC Laser System is indicated for dermatological procedures requiring the coagulation of soft tissue.

Prescription Use X

(Part 21 CFR 801 Subpart D)

AND/OR

Over The Counter Use

(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Neil R. P. Ogden
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K080932